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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,817	04/09/2004	Robert K. Schultz	2801-0187P	8899

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EXAMINER	
SILVERMAN, ERIC E	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/820,817	SCHULTZ ET AL.	
	Examiner	Art Unit	
	Eric E. Silverman	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-20 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

9.0-0

DETAILED ACTION

Receipt is acknowledged of applicant's Oath or Declaration, filed on 04/04/2004.

Specification

The abstract of the disclosure is objected to because it is not a complete sentence. The abstract is a sentence fragment and does not have a predicate. Correction is required. See MPEP § 608.01(b).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11 - 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,743,413 in view of Purewal et al., U.S. Patent 5,225,183. The instant claims are product by process claims, and are drawn to a metered dose inhaler containing a pharmaceutical suspension formulation consisting essentially of a suspension of one or more particulate drugs and a propellant selected from the groups consisting of HFC 134 a, HFC 227, and a mixture thereof. The patented claims recite a metered dose valve

containing a pharmaceutical suspension formulation where the suspension formulation consists essentially of a particulate and 1,1,1,2-tetrafluoroethane. Purewal et al. teach that HFC 134a is a synonym for 1,1,1,2-tetrafluoroethane (see column 2, lines 14-15).

The instant claims are silent with regard to the use of surfactant, and require that the propellant be selected from a group consisting of HFC 134a, HFC 227 or a mixture thereof. The patented claims require that the propellant be HFC 134a. The instant claims thus recite a genus of products, which may or may not contain surfactant, and may contain a propellant consisting of either HFC 134a alone, or HFC 227 or a mixture of HFC 134a and HFC 227. The patented claim is a species, which requires that the product contain only HFC 134a as the propellant. It would be obvious to a person of ordinary skill in the art to select to use HFC 134a alone, or HFC 227 or a mixture of HFC 134a and HFC 227 depending on which was required to give the best possible result.

Claims 11-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 5,427,282. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims recite a metered dose inhaler wherein the medicament is exclusively in a suspension, wherein the propellant is exclusively drawn from the group consisting of HFC 134 a and HFC 227 and mixtures thereof, and where the pharmaceutical formulation is provided to the product by specified methods, whereas the patented claim recites both dispersed and dissolved medicaments. Instant "medicament in suspension" is anticipated by the patented

claims. The patented claims are generic with regard to propellant. Therefore, instant specific propellants are anticipated by the patented claims as evidenced by the patented claim claim 6 of the patent, which recites several propellants including those recited by instant claim. Furthermore, although patented claim 11 is silent with regard to the presence of surfactant, it is clear that patented claim 11 is meant to include surfactant as evidenced by patented claim 11 being dependant on patented claim 6, which is further dependant on patented claim 1, which recites the presence of surfactant.

Additionally, the patented claims are generic with respect to the method by which the pharmaceutical formulation is provided to the product. However Applicant does not show the criticality of the method of providing the pharmaceutical formulation to the product. Since in a manufacturing process, one could either prepare a formulation in bulk and then dispense it into individual units one at a time by a variety of means, or prepare the components of a formulation and then add the components separately to individual units, such practices are deemed obvious manipulations practiced by a person of ordinary skill in the art.

Claims 11-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 19 of U.S. Patent No. 6,054,488. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims recite a genus of metered dose inhaler wherein the medicament is exclusively in a suspension, wherein the propellant is exclusively drawn from the group consisting of HFC 134 a and HFC 227 and mixtures thereof, and where the pharmaceutical formulation is provided to the product by

specified methods, whereas the patented claim recites a specific species of metered dose inhaler ("an aerosol dispensing device comprising a container equipped with a metered dose dispensing valve..." containing an aerosol formulation. Although the patented claim is silent with regard to the specific content of the aerosol formulation, it is clear that the formulation is meant to comprise a pharmaceutical suspension formulation consisting of 0.0025% to 0.1% w/w of micronized formoterol, from 0.1%to 5.0% w/w of ethanol, a propellant consisting of either HFA 134a, HFA 227, or a mixture thereof, and optionally a surfactant, as evidenced by the fact that the patented claim is dependant on claim 1 of the patent.

Additionally, the patented claims are generic with respect to the method by which the pharmaceutical formulation is provided to the product. However Applicant does not show the criticality of the method of providing the pharmaceutical formulation to the product. Since in a manufacturing process, one could either prepare a formulation in bulk and then dispense it into individual units one at a time by a variety of means, or prepare the components of a formulation and then add the components separately to individual units, such practices are deemed obvious manipulations practiced by a person of ordinary skill in the art.

The instant claims specify that the formulation be a suspension, are silent with regard the use of ethanol, and are further silent with regard to the specific drug to be used. The product of the patented claims require specified amounts of ethanol, and a specific drug in a specific amount, may contain a pharmaceutical formulation as a solution or suspension, and may or may not require surfactant. It would be obvious to a

person of ordinary skill in the art to choose to use a solution or a suspension, to use an appropriate amount of ethanol, to use an appropriate drug other than or including formiterol in an appropriate amount, and to use surfactant or not in the product as required with a reasonable expectation of success.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Byron et al., US Patent Number 5,182,097. Byron discloses a process of preparing a metered dose inhaler comprising the steps of first preparing a pharmaceutical suspension formulation comprising a therapeutically effective formulation of a particulate drug and a propellant consisting of HFC 134a alone or in combination with other fluorocarbons or hydrofluorocarbons, such as HFC 227, and then providing the suspension in the metered dose inhaler (see column 2, lines 47-50 and lines 56-60). Byron also discloses this process when a surfactant is included in the composition (see column 2, lines 56-60).

Although Byron does not specifically mention a metering valve which comprises a valve stem, a valve stem is well known by a person of ordinary skill in the to be an

inherent component of any metered dose valve in a metered dose inhaler. Therefore, such is implicit. Furthermore, Byron does not specifically state that the surfactant be contained in the valve stem, nor does Byron specifically state that the surfactant will act as a lubricant for said valve stem. Nonetheless, as a person of ordinary skill in the art would recognize, the design of any metered dose valve forces the pharmaceutical composition contained therein to pass into the valve stem. Therefore, any surfactant that is a component of the pharmaceutical composition, such as the disclosure of Byron, will also be contained in the valve stem, thereby serving to lubricate the valve stem. Examiner cites Hansen et al., U.S. Patent Number 3,994,421, specifically Figures 1-4 as a teaching in this context.

Byron further discloses the process and product of the metered dose inhaler where the pharmaceutical suspension formulation is provided to the inhaler by either preparing the pharmaceutical composition in bulk and then adding to the inhaler or by preparing the composition in the container (see column 5 line 58 – column 6 line 6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Purewal et al., U.S. Patent Number 5,225,183 by itself or in view of Byron. Purewal teaches a the product and process of a pharmaceutical suspension formulation in a

container with an aerosol valve, wherein the surfactant formulation comprises a medicament, a surfactant, 1,1,1,2-tetrafluorethalene, also called HFC 134a or Propellant 134a (see column 2, lines 10-13).

Purewal does not teach the process or product of the formulation in a metered dose inhaler. However, Purewal does teach the process and product of the formulation in an aerosol (see column 7, lines 12-15), and that metered dose inhalers have been well known in the art for more than fifty years (see column 1, lines 14 – 15). Purewal also does not teach specific methods of providing the formulation to a metered dose inhaler.

The teachings of Byron are discussed above.

Instant claims recite the product and process of a metered dose valve containing a suspension formulation which in some cases must comprise a surfactant and in which a surfactant is optional in other cases, which may comprise HFC 134a alone or HFC 227 alone or a mixture thereof, which comprises a drug, and which may be prepared by a variety of specified means.

Therefore, it would have been prime facie obvious to a person of ordinary skill in the art at the time of the invention to use the formulation of Purewal in the formulation in a metered dose valve and to prepare the metered dose valve by one of the means specified. The motivation is provided by Purewal's teaching that metered dose valves have been known in the art for about fifty years. A person of ordinary skill in the art would be motivated with a reasonable expectation of success to use a compound with a higher polarity than. A person of ordinary skill in the art would also find it obvious to use

any number of methods to provide the pharmaceutical formulation to the metered dose inhaler, and Applicant has not showed any criticality to the particular means recited in instant application. In a manufacturing process, both preparing a formulation in bulk and then providing it to the individual units or preparing the components of the formulation separately and then providing said components to the units one at a time would be routine manipulations practiced by a person of ordinary skill in the art with a reasonable expectation of success. The teachings of Byron show that both of these are within the skill of a person of ordinary skill in the art.

Conclusion

The following prior art is made of record and not relied upon is considered pertinent to applicant's disclosure: Hansen et al., U.S. Patent Number 3,994,421, Jinks et al. U.S. Patent Number 4,810,488, Bodor, U.S. Patent Number 4,710,495, Badger et al., U.S. Patent Number 4,963,557, Byron et al. U.S. Patent Number 5,190,029, Schultz et al., U.S. Patent Number 5,118,494, and Purewal et al., U.S. Patent Number 5,225,097.

None of the claims are allowed. None of the claims are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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